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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,915	12/23/2004	Kiichiro Yano	053466-0391	7057
22428 7590 02/07/2008 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER CLARK, AMY LYNN	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 02/07/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/518,915	Applicant(s) YANO ET AL.	
	Examiner Amy L. Clark	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/11/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 11 October 2007 with the amendment of claim 4.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4 and 5 are currently pending and under examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed with this application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11 October 2007 was filed after the mailing date of the non-final rejection on 12 April 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please note that reference C3 under "Foreign Patent Documents" was not considered, as indicated with a line through the reference, because no English translation of the reference was provided by Applicant.

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 4 and 5 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth in the paper mailed on 12 April 2007 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 11 October 2007.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

In the instant case, the original Claim 4 did not disclose the exact total amount of the mixture of ingredients, wherein Applicant claimed, as Claim 4, "A method for inhibiting aging, comprising the step of applying the anti-aging preparation according to claim 2 onto the skin". Claim 5 also did not originally provide the amount of the mixture of ingredients was not previously disclosed in this claim or any previously pending claims. In amended Claim 4, Applicant claims, "A method of inhibiting photoaging, comprising the step of applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance

based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract” and in newly submitted Claim 5, Applicant claims, “The method of claim 4, wherein the one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition”, thereby introducing a specific volume of a mixture of crude drugs, wherein it appears that Applicant is claiming that all of the drugs when combined are present in a total amount of 0.0001 to 20.0% by mass as a dry substance based on the total weight of the composition and that Applicant is claiming that all of the drugs when combined are present in a total amount of 0.0001 to 10.0% by mass as a dry substance based on the total weight of the composition, which is considered to be new matter. Insertion of the above mentioned claim limitation has no support in the as-filed specification. Page 9, lines 2-7 (paragraph 0033 of the PreGrant Publication) of the specification discloses, “The formulating amount of the agent having angiogenesis inhibitory activity in the angiogenesis inhibiting preparation or the anti-aging preparation according to the present invention is 0.0001 to 20.0% by mass, preferably 0.0001 to 10.0% by mass, as a dry substance based on the total amount of the composition”. This is not sufficient support for the new genus: “A method of inhibiting aging, comprising the step of applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and

silk extract", in Claim 4 and in newly submitted Claim 5, "The method of claim 4, wherein the one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition". This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Applicant argues that the specification provides support for the phrase, "wherein the one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition".

However, this is not found persuasive because while the specification does provide support for "The formulating amount of the agent having angiogenesis inhibitory activity in the angiogenesis inhibiting preparation or the anti-aging preparation according to the present invention is 0.0001 to 20.0% by mass, preferably 0.0001 to 10.0% by mass, as a dry substance based on the total amount of the composition", this refers to

an individual agent, not a combination of crude drugs. The specification does disclose what Applicant regards as "an agent" in the last two lines of the specification, where Applicant discloses, "Agents, which induce TSP-1 and induce apoptosis of vascular endothelial cells, such as da zao extract, ginseng extract, roman chamomile extract, chlorella extract, celery extract, parsley extract, coicis semen extract, and silk extract". However, Applicant is disclosing in the specification that one of these agents (or each of these individual agents) is present in an amount of 0.0001 to 20.0% by mass, preferably 0.0001 to 10.0% by mass. Please note that this does not provide support for a combination of crude drugs, wherein the entire percent of these ingredients combined is that disclosed amount. If Applicant is intending that each of the crude drugs is present in the range claimed by Applicant, then the claim should be amended to reflect this because as the claim currently reads, it appears that Applicant is saying that either one crude drug is present in the amount claimed, which is supported by the specification, or that there are several drugs when combined are present in a total amount of the range claimed, and this part of the phrase is not disclosed in the specification.

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 11 October 2007, with respect to the rejection of claims 4 and 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement have been fully considered and are persuasive. The rejection of claims 4 and 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn.

Claim Rejections - 35 USC § 101

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 11 October 2007, with respect to the rejection of claims 4 and 5 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility have been fully considered and are persuasive. The rejection of claims 4 and 5 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility has been withdrawn.

Claim Rejections - 35 USC § 102

Claims 4 and 5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kitada et al. (N*, JP 10-017459 A).

Kitada teaches a method of improving dullness from skin aging comprising administering a composition to skin comprising one or more ununiformity improvement enhancement agents of the suitable skin concerned to carry out improvement prevention of the dullness resulting from the ununiformity improvement agent of the skin, aging, etc, wherein the heterogeneity improvement agent of the skin the essences, which is the processed product and/or the solvent extract or its solvent-removed product of the plant, and their fractions of *Panax ginseng* Meyer and *Zizyphus jujuba* Mill. Kitada further teaches that the heterogeneity comprises 0.001-10% of the weight of the

composition (See Abstract, paragraphs 0001, 0005-0007, 0017, 0026 and Example, paragraphs 0027-0037, particularly paragraph 0037).

The method of using the referenced composition is not expressly taught as a method of inhibiting photoaging. However, the instantly claimed process involves the step of applying to skin a composition comprising one or a plurality of crude drugs, wherein the crude drug may be *Panax ginseng* and *Zizyphus jujuba*, and, furthermore, the amounts of the extract applied to the skin are the same as that claimed by Applicants. Thus, the functional effect of inhibiting photoaging is inherent to the method of using the composition taught by Kitada.

Therefore, the reference anticipates the claimed subject matter.

Applicant argues that the reference is silent in respect of inhibiting or preventing skin damage caused by exposure to sunlight.

However, this is not found persuasive because the claimed functional effects are inherent to the extract taught by Kitada, as set forth above.

Claims 4 and 5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ito et al. (O*, JP 08-109122 A).

This rejection is maintained for reasons of record set forth in the paper mailed on 12 April 2007 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 11 October 2007.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Ito teaches a method of improving the skin by inhibiting wrinkles comprising the step of applying a composition comprising an extract of *Anthemis nobilis* L. in an amount of 0.01-10 wt% to skin (See Abstract and paragraphs 0006, 0011 and 0019-0037).

The method of using the referenced composition is not expressly taught as a method of inhibiting photoaging. However, the instantly claimed process involves the step of applying to skin a composition comprising one or a plurality of crude drugs, wherein the crude drug may be *Anthemis nobilis*, and, furthermore, the amounts of the extract applied to the skin are the same as that claimed by Applicants. Thus, the functional effect of inhibiting photoaging is inherent to the method of using the composition taught by Ito.

Therefore, the reference anticipates the claimed subject matter.

Applicant argues that the reference is silent in respect of inhibiting or preventing skin damage caused by exposure to sunlight.

However, this is not found persuasive because the claimed functional effects are inherent to the extract taught by Ito, as set forth above.

Claims 4 and 5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Matsui et al. (P*, JP 05-032537 A).

This rejection is maintained for reasons of record set forth in the paper mailed on 12 April 2007 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 11 October 2007.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Matsui teaches a method of improving the skin by inhibiting wrinkles comprising the step of applying a composition comprising 0.5-4wt % silk fiber to skin (See Abstract and paragraphs 0018-0033).

The method of using the referenced composition is not expressly taught as a method of inhibiting photoaging. However, the instantly claimed process involves the step of applying to skin a composition comprising one or a plurality of crude drugs, wherein the crude drug may be silk fiber, and, furthermore, the amounts of the extract applied to the skin are the same as that claimed by Applicants. Thus, the functional effect of inhibiting photoaging is inherent to the method of using the composition taught by Matsui.

Therefore, the reference anticipates the claimed subject matter.

Applicant argues that the reference is silent in respect of inhibiting or preventing skin damage caused by exposure to sunlight.

However, this is not found persuasive because the claimed functional effects are inherent to the extract taught by Matsui, as set forth above.

Claims 4 and 5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kitada et al. (Q, JP 10-017458 A). Newly applied as necessitated by amendment.

Kitada teaches applying an extract of *Zizyphus jujuba*, wherein the extract is obtained by extracting *Zizyphus jujuba* with aqueous ethanol and distilling off the solvent to provide the extract (See Example 3 of manufacture on page 2), which reads on dry substance, to the forearm of a person after the skin of the forearm was exposed to UV-B light, wherein exposure to UV-B light provided darkening of the skin and that improvement on the skin after applying the extract of *Zizyphus jujuba* was observed (See page 4, paragraph 0025, "Example 8"). Kitada further teaches that the extract is present in an amount of 0.001-10 wt % of the composition (See abstract), which reads on one crude drug is present in the amount of 0.0001 to 10 by mass %.

The method of using the referenced composition is not expressly taught as a method of inhibiting photoaging. However, the instantly claimed process involves the step of applying to skin a composition comprising one or a plurality of crude drugs, wherein the crude drug may be *Zizyphus jujuba*, and, furthermore, the amounts of the extract applied to the skin are the same as that claimed by Applicants. Thus, the functional effect of inhibiting photoaging is inherent to the method of using the composition taught by Kitada.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 4 and 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tominaga (A*, US Patent Number: 5,747,049), in view of Kitada et al. (N*, JP 10-017459 A), Ito et al. (O*, JP 08-109122 A), Fugitani et al. (R*, JP 11-228437 A), and Matsui et al. (P*, JP 05-032537 A).

This rejection is maintained for reasons of record set forth in the paper mailed on 12 April 2007 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 11 October 2007.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Tominaga teaches a method of inhibiting cutaneous aging comprising applying an effective amount of an anti-aging composition to skin comprising one or two aminoethyl compounds and further comprising ginseng extract and coicis semen (*Coix lachryma-jobi*) extract (See claim 1 and column 6, lines 63-65).

The method of using the referenced composition is not expressly taught as a method of inhibiting photoaging. However, the instantly claimed process involves the step of applying to skin a composition comprising one or a plurality of crude drugs, wherein the crude drug may ginseng extract and coicis semen (*Coix lachryma-jobi*) extract, which is one and the same as the method of applying the composition as

claimed by Applicants. Thus, the functional effect of inhibiting photoaging is inherent to the method of using the composition taught by Kitada.

The teachings of Kitada are set forth above and applied as before.

The teachings of Ito are set forth above and applied as before.

Fugitani teaches a method of inhibiting aging in skin comprising applying a composition comprising extract of chlorella (See abstract and paragraphs 0008-0012 and 0030-0046).

The teachings of Matsui are set forth above and applied as before.

Tominaga does not teach a composition comprising a plurality of all of the crude drugs, wherein the combination of these drugs is present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, nor that the combination of a plurality of all of the crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine ginseng extract and coicis semen (*Coix lachryma-jobi*) extract in a composition for application to the skin to treat and inhibit aging of the skin, as shown in Tominaga, wherein the composition intrinsically inhibits photoaging and to modify the composition to include da zao extract, roman chamomile extract, chlorella extract, and silk extract for the same effect, as taught by Ito, Fugitani, and Matsui. One would have been motivated to use the claimed ingredients, commonly known for treating and inhibiting skin aging, for inhibiting photoaging because the claimed ingredients can be applied to the skin and are known to have beneficial

properties relating to skin and because each of the claimed ingredient intrinsically inhibit photoaging, as shown above. Furthermore, one of ordinary skill in the art would have reasonable expectation of success in using such a composition for treating and inhibiting skin aging, which intrinsically includes inhibiting photoaging, because the beneficial properties of the ingredients are taught by the cited references.

It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach that extracts of da zao, ginseng, Roman chamomile, chlorella, coicis semen and silk extract are effective ingredients in compositions for treating signs of aging in skin, it would have been obvious to combine these ingredients with the expectation that such a combination would be effective in skin care compositions and for treating aging skin and that these ingredients would intrinsically inhibit photoaging. Thus, combining them flows logically from their having been individually taught in prior art.

Furthermore, it would have been obvious to one of ordinary skill in the art and would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the composition used in the method taught by Tominaga by adjusting the amounts of each beneficial extract to provide the instantly

claimed invention because at the time the invention was made, a method for inhibiting aging in skin by applying extracts of da zao, ginseng, Roman chamomile, chlorella, coicis semen and silk extract was known, and, furthermore, each of these extracts intrinsically inhibit photoaging.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant argues that none of the references teach inhibiting or preventing skin damage caused by exposure to sunlight (photoaging).

However, this is not found persuasive because the claimed functional effects are inherent to the extracts taught by each of the claimed references, as set forth above.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Amy L. Clark
AU 1655

Amy L. Clark
January 23, 2008


MICHELE FLOOD
PRIMARY EXAMINER